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GUEST COMMENTARY

Commentary on the Objectives and Efficacy of Proficiency Testing in Microbiology

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In a recent guest commentary, Isenberg and D'Amato (7) questioned whether proficiency testing of microbiology laboratories is an effective method for improving their overall clinical capabilities and whether it is an appropriate regulatory tool for measuring their performance. As laboratorians directly involved in the technical and administrative components of the New York State Proficiency Testing Program, we believe that it is essential to provide alternative views on many of the issues and suggestions presented by those authors in their commentary. It is our intent to discuss a different perspective of the objectives of proficiency testing and the efforts made by those involved in the New York program to ensure that it meets established goals.

The authors suggest in their commentary that the most important measure of a microbiology laboratory's performance is its ability to "provide meaningful information for a physician treating a patient." We agree that accurate clinical laboratory data are important factors in patient management, but would suggest that external proficiency testing provides an effective, objective means of assessing this capability. We recognize that no proficiency testing program can measure the participating laboratories' capabilities to perform each of the numerous individual procedures involved in processing clinical specimens. However, these programs can evaluate the ability of laboratories to correctly identify clinically important microorganisms and to differentiate them from routine contaminants, which are critical factors required by physicians in treating their patients.

By focusing their commentary on the assessment and regulatory aspects of proficiency testing, the authors fail to recognize that proficiency testing programs are also educational tools and should serve as important components in quality improvement programs. First, specimens submitted to laboratories as part of the test events expose laboratorians to a wide variety of clinically relevant microorganisms, some of which may not be seen in routine day-to-day laboratory operations. Some have argued that such uncommon potential pathogens should not be used in test programs. However, in this era of ever increasing nosocomial infections caused by emerging pathogens, the unusual or rarely recovered microbial pathogen of today frequently becomes the routinely encountered isolate of the future (1, 4, 5). To demonstrate the educational potential of proficiency testing, we note that when a culture of *Beauveria* spp. was first presented as an ungraded specimen to laboratories participating in the mycology program, only about 50% of those responding were able to correctly identify the mold. However, when the fungus was again sent to the same laboratories, approximately 2 years after their initial educational exposure, more than 85% of the facilities were able to identify the organism as a graded test specimen.

In addition, many proficiency test programs publish critiques that summarize the test results of all participating laboratories, provide information on various methods that may be used in the recovery and identification of the test specimens, and cite recent relevant reports in the literature on the test specimens and/or new diagnostic techniques. These critiques are frequently used as part of the in-service training programs of laboratory personnel.

Second, proficiency programs, within the inherent limitations of the testing format, give laboratory directors and administrators an additional mechanism for assessing the capabilities of their personnel and their performances in comparison with those of the staff of other clinical facilities. Furthermore, the discussions in the critiques of various procedures, stains, instrumentation, etc., used in identifying test specimens allow laboratorians to more effectively evaluate similar diagnostic products used in their laboratories. Both of these applications of test critiques extend and enhance the quality improvement procedures used by participating laboratories (8–10).

The authors of the previous commentary (7) noted that the test specimens in microbiology proficiency test events do not reflect actual clinical laboratory experience, in that primary specimens are at "risk of contamination with exogenous organisms from usually contaminated areas. This situation is not commonly reflected in proficiency test samples." However, the federal regulations which implement the Clinical Laboratory Improvement Amendments of 1988 (CLIA 1988) require that a minimum of 50% of all microbiological test specimens be composed of mixed flora appropriate to the listed sources (6). In addition, the providers must indicate which of the specimens will be mixed with contaminating flora and also the identity of the contaminants. We would agree with Isenberg and D'Amato (7) that test samples prepared in the laboratory are not totally reflective of "true" laboratory conditions, in that these samples may contain microbial concentrations in excess of those encountered in routine primary specimens. However, the test specimens provided by all approved proficiency testing programs are required to simulate clinical conditions in that they contain appropriately mixed flora that meet stringent federal standards.

The authors intimate that proficiency programs are reluctant "to accommodate emerging methodologies to detect and identify organisms" and that in so doing the programs are "detrimental to laboratories' efforts to remain *au courant*." In fact, the New York State program makes every effort to ensure that test specimens may be identified through virtually any method currently used in clinical microbiology laboratories. For exam-

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ple, in the New York State bacteriology program, gonorrhea test specimens were evaluated for compatibility with the Gen-Probe PACE 2 kit when this product was initially approved by the federal Food and Drug Administration for use as a diagnostic tool. Through these investigations, the program was able to ensure that participating laboratories could appropriately identify the test organisms with this new commercially available product. As another example, the mycology program identifies all yeastlike specimens with the most commonly used commercially available identification kits and all mold samples with a variety of nutrient media prior to their use in test events. In addition, potential test organisms are sent to reference laboratories that are acknowledged leaders in the area of medical mycology. These clinical facilities, using state-of-the-art methods, identify the test specimens and submit their results to the program. Unanimous agreement of all reference laboratories as to the identity of the specimens must be achieved before the samples are used in test events. Participating laboratories are not constrained, either deliberately or unintentionally, in the diagnostic tools that they may use to identify test specimens. They may use the newest products and instrumentation that are appropriate to the cost constraints and the volume of specimens processed in their facilities.

The authors' commentary (7) reiterates a very commonly held myth that unsuccessful performance in proficiency test events will cause "the draconian measure of potential loss of license." First, laboratories do not lose their CLIA certification and/or state license or permit owing to their failure in a single test event. In New York State, such unsuccessful performance in one event merely results in a letter from the specific test program in which the program director offers assistance to the laboratory in correcting the problems that contributed to its failure. In addition, CLIA 1988 regulations describe a graduated series of penalties, the last and most severe of which is the loss of the laboratory's CLIA certification. Furthermore, it is impossible for a laboratory to lose its license or permit owing solely to poor proficiency test performance. Although laboratories may be required to cease the testing of patient specimens until they have remediated the problems that caused them to fail two of three consecutive test events, they will not lose their license or permit and will be allowed to resume testing specimens once they have demonstrated that they have corrected their proficiency deficiencies. In New York State, less than 1% of the laboratories participating in any given test program are required to cease the testing of clinical specimens due to their unsuccessful performances in two of three test events. Several other factors, such as (i) the results of on-site surveys of the physical facility, (ii) repeated uncorrected deficiencies in staffing, reagents, and instrumentation, and (iii) violations of state and federal civil and criminal laws, in combination with poor performance in test events, are needed to initiate proceedings against a laboratory to remove its license or permit.

The authors note in their commentary (7) that "the laboratory's failure to reach the same consensus as that of the reference laboratories [in this context, reference and referee laboratories are being used as synonymous terms] does not necessarily reflect on the quality of the testee laboratory. Variables such as the quality of the specimen, transportation, environmental conditions, and human error can all impact on the laboratory's efforts to perform at an acceptable level."

The New York State bacteriology program has evaluated several of the alternate factors noted by the authors in order to minimize their effects on the grading of participating laboratories. For several years, the program ships duplicate sets of test specimens to selected participating laboratories within and outside of the state and requests that the second set be returned (at no expense to the laboratories) to the state bacteriology laboratory. The returned test samples are then processed and the results are compared with the initial identifications. If discrepancies in the identifications are found to be caused by external variables, the questionable specimen will be considered "ungradeable," and in accordance with current CLIA 1988 regulations, the specimen will be deleted from the test event.

Thus, the only variable noted by the authors (7) that could affect a laboratory's performance and that is beyond the quality control of the proficiency testing program is human error. The latter is, of course, one of the many components involved in processing specimens that are assessed by proficiency testing.

It should be noted that the use of referee laboratories (defined by Isenberg and D'Amato [7] as reference laboratories) in determining the gradeability of test specimens is required by CLIA 1988 regulations. In addition, in contrast to the statements made by the authors in their commentary, the authentication of any microbial specimen is not solely dependent upon the consensus of 90% of the referees as to the identification of the microorganism. A test specimen is considered to be gradeable and its identification authenticated if 90% of the referee laboratories *or* 90% of all participating laboratories are in agreement on its identification. Therefore, even if 90% of the referee laboratories could not reach a consensus on the identification of a microbial sample, that sample could be graded if 90% of all laboratories participating in the test event agreed on the identification. We believe that not only is this system extremely fair to the participating laboratories but it also further diminishes or eliminates the potential effects on grading caused by the external variables that were the focus of the concerns of the authors' commentaries.

Many other components of proficiency testing programs that the authors criticize are mandated by CLIA 1988 regulations: for example, the number of test events per calendar year, the grading formulas used in each specialty or subspecialty, the specific designation of clinical tests as being of moderate or high complexity, and the processing procedures for test specimens. We agree that many of these CLIA 1988 requirements are not supported by extensive studies in the current scientific literature. As a consequence, several test specialties within the New York proficiency program are currently evaluating CLIA 1988 test standards to determine their validity.

In addition, we agree with Isenberg and D'Amato (7) that "it is common for a laboratory to be subjected to inspection by several agencies, each of which has its own agenda, attitude, and fees. This needless duplication leads to confusion and waste of limited time and money." In many instances such duplicate on-site surveys are required by the professional organizations that accredit the laboratories, and in other cases the directors or administrators choose to use more than one inspection organization as part of their quality assurance programs. However, New York State recognizes that such duplicative inspections may have a detrimental affect on the "overburdened laboratory struggling to preserve rapidly diminishing resources" described by the authors. Consequently, the Clinical Laboratory Evaluation Program, the unit within the Department of Health that administers laboratory accreditation, is pursuing discussions with the College of American Pathologists and the American Society of Histocompatibility and Immunochemistry and is initiating efforts with the Joint Commission on Accreditation of Healthcare Organizations to establish cooperative relationships to decrease the drain on financial resources and the disruption of laboratory activities created by multiple surveys. These exchanges between this

state's regulatory agency and several professional groups may eventually contribute to a general consensus on inspection standards, the nature of sanctions to be brought against poorly performing laboratories, and other modifications of current assessment programs as described in the commentary.

The authors (7) suggest that if the changes in accreditation and regulatory programs which they recommend were made, such revisions "could lead to the development of self-regulation, employing the emerging quality improvement department of most medical facilities." However, voluntary testing programs or self-regulation has previously been attempted in several states. Studies of these types of programs have demonstrated that mandated proficiency testing enhances the overall quality of clinical laboratory testing, including turnaround time, accuracy of results, and training of laboratorians. Voluntary or self-regulations have universally been found to be incapable of achieving these goals (2, 3).

In addition, self-regulation does not recognize the fact that there are clinical laboratories which cannot appropriately identify potential pathogens due to the use of inappropriate procedures, out-of-date reagents, uncontrolled instrumentation, and/or incompetent staff. On-site surveys have demonstrated that some laboratories may not even be aware of their inability to adequately conduct clinical tests. Alternatively, the directors and/or administrators of a small number of facilities are aware of their poor performance, but attempt to continue to operate, in violation of federal and state statutes and regulations, solely to obtain reimbursements for their testing. Mandated proficiency test programs can assist laboratories in discovering problems in their test methods that are not detected by their quality control and assurance procedures. Furthermore, proficiency testing has provided essential evidence in civil and criminal proceedings brought against unethical laboratories.

In conclusion, we are aware of the flaws in proficiency testing, especially as it is currently used in the area of microbiology, and we further acknowledge that these programs provide only imperfect methods of measuring the performance of clinical laboratories. However, we believe that the programs do provide an effective means of ensuring, on a continuing basis, that the public will receive accurate test results provided by trained and experienced technical personnel. Obviously, the programs can and are being modified in order to develop more precise mechanisms for evaluating the overall capabilities of participating laboratories. As we have described, the New York State program is engaged in discussions to reduce the regulatory burden on permit-holding laboratories and is constantly modifying its procedures to accommodate the introduction of new diagnostic techniques. Finally, it is our opinion that, despite its imperfections, proficiency testing, when used as intended, in consort with other assessment and training methods, does meet its objectives of providing a regulatory, educational, quality-improvement mechanism for clinical microbiology laboratories.

REFERENCES

1. **Bergogne-Berezin, E., and K. J. Towner.** 1996. *Acinetobacter* spp. as nosocomial pathogens: microbiological, clinical, and epidemiological features. Clin. Microbiol. Rev. **9:**148–165.
2. **Boone, D. J.** 1993. Governmental perspective on evaluating laboratory performance. Clin. Chem. **39:**1461–1465.
3. **Crawley, R., R. Belsey, D. Brock, and D. M. Baer.** 1986. Regulation of physician office laboratories, the Idaho experience. JAMA **255:**374–382.
4. **Falkinham, O., III.** 1996. Epidemiology of infection by nontuberculous mycobacteria. Clin. Microbiol. Rev. **9:**177–215.
5. **Fridkin, S. K., and W. R. Jarvis.** 1996. Epidemiology of nosocomial fungal infections. Clin. Microbiol. Rev. **9:**499–511.
6. **Health Care Financing Administration, U.S. Department of Health and Human Services.** 1993. 42 CFR 493. Laboratory requirements. U.S. Government Printing Office, Washington, D.C.
7. **Isenberg, H. D., and R. F. D'Amato.** 1996. Does proficiency testing meet its objective? J. Clin. Microbiol. **34:**2643–2644.
8. **Kafka, M. T.** 1988. Internal quality control, proficiency testing, and the clinical relevance of laboratory testing. Arch. Pathol. Lab. Med. **112:**449–453.
9. **Lawson, N. D., B. F. Gilmore, and D. W. Tholen.** 1988. Multiprogram characterization of laboratory bias, precision, and total error. Proposal for improved assessment with shared external and expanded internal (regional) quality control pools. Arch. Pathol. Lab. Med. **112:**454–461.
10. **Richman, W. J., C. Monical, and M. J. Waxdal.** 1993. Improved precision in the enumeration of absolute numbers of lymphocyte immunophenotypes with long-term monthly proficiency testing. Ann. N. Y. Acad. Sci. **667:**53–58.

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